

EFFICACY REVIEW

PRODUCT: SVP7

FILE SYMBOL: 83399-A

DATE: 06/14/07

DP BARCODE: D340612

DECISION NUMBER: 373247

GLP: N/A

CHEMICAL: Permethrin (36.08%)
Dinotefuran (4.95%)
Pyriproxyfen (0.44%)

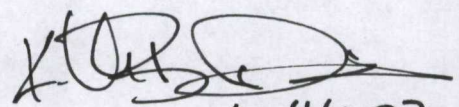
CHEMICAL NUMBER: Permethrin.....109701
Dinotefuran.....044312
Pyriproxyfen....129032

PURPOSE: Review of label to determine acceptability of new label claims.

MRID: N/A

TEAM REVIEWER: Rita Kumar

EFFICACY REVIEWER: Kable Bo Davis, M.S., Entomologist


6-14-07

BACKGROUND:

SVP7 is intended for the treatment and prevention of ticks, fleas, and mosquitoes on dogs and puppies over seven weeks of age. The application rate is: 0.06 fl oz for weights 2.5 to 20 lbs., 0.12 fl oz for weights 20 to 55 lbs, 0.16 fl oz for weights 56 to 95 lbs, and 0.3 fl oz for over 95 pounds. The directions for use state that to part the hair between the shoulder blades and to slowly apply the product to the skin until the applicator is completely empty. The number of spots to apply varies upon the weight of the dog. The product should be repeated monthly, and must never be used on other animals, including cats.

RECOMMENDATIONS:

1. All references to lice must be deleted from the label. To have lice added back on, acceptable efficacy data must be submitted.

2. All references to the diseases anaplasmosis and cytauxzoonosis must be deleted from the label.
3. The following claims are considered heightened efficacy and must be deleted from the label.
 - *"Kills (virtually) all fleas in 6 hours"*
 - *"SVP7 contains the insecticide dinotefuran, a neonicotinoid with rapid knockdown effect."*
 - *"New complete flea, tick, mosquito and lice control (first 6 months)"*
 - *"Rapid kill of fleas, ticks, lice and mosquitoes is important in the prevention of disease transmission by these parasites"*
 - *"Kills ticks which carry disease"*
 - *"Pyriproxyfen has an anti-feeding effect on adult fleas, thereby preventing the flea from taking a blood meal"*
4. The following claims must be deleted from the label or include a disclaimer stating that they do not apply to dogs weighing over 95 pounds.
 - *"Kills 96% of fleas in 6 hours"*
 - *"Quick onset of activity (kill) within 2 hours"*
 - *"Kills newly emerged fleas before they lay eggs"*
 - *"SVP7 contains dinotefuran, a "NEW first 6 months) neonicotinoid insecticide with knockdown in less than 2 hours"*
 - *"Dinotefuran kills fleas within 6 hours"*
 - *"Kills fleas, ticks, lice and mosquitoes before they lay eggs"*
 - *"Kills over 95% of fleas in 6 hours and up to 100% in 12 hours"*
 - *"Kills fleas before they lay eggs"*
 - *"Kills and repels fleas before they lay eggs"*
 - *"Kills and repels ticks within 24 hours"*
 - *"Kills ticks [in 24 – 48 hours] before they can transmit Lyme disease"*
 - *"Kills ticks [in 24 – 48 hours] before they can transmit Ehrlichia"*
 - *"Kills ticks before they can lay eggs"*
 - *"Repels and kills up to 100% of mosquitoes for at least one month"*
5. Revise the statements *"DO NOT USE ON CATS. Due to their unique physiology and inability to metabolize certain compounds – THIS PRODUCT MUST NOT BE USED ON CATS. Accidental application to cats, and/or grooming a recently treated dog, this product may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided."* to read *"DO NOT USE ON CATS. Due to their unique physiology and inability to metabolize certain compounds, this product must not be used on cats. If applied to a cat, or ingested by a cat that actively grooms a recently treated dog, this product may have serious harmful effects. If this occurs contact your veterinarian immediately."*